Remarks

Applicant believes that this amendment places the subject application in better condition for allowance and in so doing introduces no new issues. Therefore, entry of this amendment, reconsideration of the application, and allowance of all claims pending herein is respectfully requested.

Claims 1-43 were originally presented in the subject application. Claims 1 and 15 have been amended. Claims 29-43 have been withdrawn due to a previous restriction requirement. Claims 1-28 remain in this case.

The Examiner's concerns are addressed separately below in the order raised in the outstanding Office Action. No new matter has been added.

Rejections under 35 U.S.C. §102(b)

Howard, III (U.S. Patent No. 5,945,341)

Claims 1, 2, 8, 9, 15, 16, and 23-28 stand rejected under § 102(b) as anticipated by Howard, III, U.S. Patent No. 5,945,341 (Howard '341). To the extent deemed pertinent in light of the amended claims, Applicant respectfully traverses this rejection.

Applicant's specification incorporates aspects of Howard et al. '341, as follows.

> An example of a reflectance spectrometer that is able to detect a misplaced strip is the CLINITEK.RTM. 50 and the CLINITEK.RTM. 500. An example of the diagnostic test strip used in accordance with this instrument is the MULTISTIX.RTM. reagent strip commercially available from Bayer Corporation. The CLINITEK.RTM. instrument and the MULTISTIX.RTM. strip are described in U.S. Pat. No. 5,945,341 and shown in FIGS. 1-4, as described in detail below.

(App. p.7 lines 1-5). Applicant's invention discloses embodiments with additional features beyond those of Howard '341, such as those shown in Applicant's Fig. 7. These new aspects of Applicant's invention include determining that the test strip is misidentified in the event the infrared reflectance of one or more reagents is outside of the acceptable predetermined range.

The independent claims reflect these aspects of Applicant's invention. Amended claim 1

recites "determining if the infrared reflectance of one or more reagents is within an acceptable predetermined range;" and "determining that the test strip is misidentified in the event said infrared reflectance of one or more reagents is outside of the acceptable predetermined range." Claim 8 similarly recites "determining if said infrared reflectances are within an acceptable predetermined range;" and "determining that said test strip is misidentified in the event said infrared reflectances are outside of the acceptable predetermined range." Amended claim 15 recites "f) determining that said test strip is misidentified in the event said infrared reflectances from said test fields are outside of the predetermined range." Support for these amendments may be found in the original disclosure, including previously presented claims 1 and 8, and the above-referenced Fig.7.

Howard '341 therefore does not anticipate the amended independent claims. Howard '341 does not disclose determining whether the strip has been misidentified, based on the infrared reflectances of the reagent (test) fields, as claimed. Instead, Howard '341 discloses confirming the identification of the strip based on a coded sequence of marker fields, rather than based on the reagent / test fields.

Howard '341 Fig. 7, step 309, "Is the color sequence known," refers to the color coded sequence of the identification bar code, referred to in step 303, "Measure color of first bar code stripe," step 304, "Is [bar code] stripe white?," and step 307, "Measure color of next bar code stripe." Howard '341 makes clear that the bar code is for identification purposes, stating, "the instrument positions the read head relative to strip 22 at the location of the identification (ID) bar code 504 and determines the spectral signature by analysis of the spectral reflectance values." (Howard '341 col. 4 lines 2-5).

Moreover, Howard '341's error reporting step 310 is not based on measuring reflectances of one or more reagents, as claimed. Rather, Howard '341's error reporting step 310 is based solely on reading reflectances of an identification bar code stripe, as discussed above. Howard '341 Fig. 7 shows that the identification step, step 309, "Is the color sequence known," occurs as a result of the steps involving measuring the reflectance of the bar code (identification) stripe: specifically, step 303, "Measure color of first bar code stripe," step 304, "Is [bar code] stripe white?," step 307, "Measure color of next bar code stripe," and step 300, "Last bar code stripe?".

Therefore, Howard '341 does not anticipate determining whether a test strip has been misidentified based on whether the infrared reflectances of reagents are within an acceptable predetermined range, as claimed.

Patel et al. (WO 9607908)

Claims 1, 2, 8, and 9 stand rejected under § 102(b) as being anticipated by Patel et al., WO 9607908. To the extent deemed relevant in light of the amended claims, Applicant respectfully traverses this rejection. As discussed above, amended claim 1, from which claim 2 depends, recites "determining if the infrared reflectance of one or more reagents is within an acceptable predetermined range;" and "determining that the test strip is misidentified in the event said infrared reflectance of one or more reagents is outside of the acceptable predetermined range." Amended claim 8, from which claim 9 depends, recites "determining if said infrared reflectances are within an acceptable predetermined range;" and "determining that said test strip is misidentified in the event said infrared reflectances are outside of the acceptable predetermined range."

Patel et al. do not disclose determining if a test strip has been misidentified. Moreover, Patel et al. do not disclose such a misidentification step based on determining whether infrared reflectances from test / reagent areas are within an acceptable predetermined range. Patel et al. focus their disclosure on the problem of correctly aligning a strip in a strip reader, rather than on checking for misidentification of the strip. Patel et al. state "a strip, method, and apparatus are provided ... wherein means are provided for rapidly and simply affirming that the strip has not been inserted upside down with respect to the optics of the apparatus." (Patel et al. p. 9 lines 3-4, 6-9). Moreover, Patel et al. disclose in a cited passage that their apparatus may be programmed so that a properly inserted strip causes "a sharp [expected] drop" and "failing to detect such a drop, report that the strip has been inserted improperly." (Patel et al. p. 25, lines 14-19).

Patel et al. therefore teaches determination of improper placement of a test strip, rather than determining whether a test strip has been misidentified, as claimed. As such, Patel et al. do not anticipate the rejected claims.

Howard III et al. (U.S. No. 5,654,803)

Claims 15-17, 23-25, and 28 stand rejected under § 102(b) as anticipated by Howard III et al., U.S. Patent No. 5,654,803 (Howard et al. '803). To the extent deemed relevant in light of amended claim 15, Applicant respectfully traverses this rejection. Amended claim 15, from which claims 16-17, 23-25, and 28 depend, recites "f) determining that said test strip is misidentified in the event said infrared reflectances from said test fields are outside of the predetermined range."

Howard et al. '803 do not disclose any steps of determining whether a strip has been misidentified. Moreover, Howard et al. '803 do not disclose effecting such a determination based on whether the infrared reflectances of the test / reagent fields are within an acceptable predetermined range. For at least these reasons, Howard et al. '803 do not anticipate claim 15.

Rejections under 35 U.S.C. §102(e)

Corey et al., U.S. Patent No. 6,316,264

Claims 1-3, 5, 7-10, 12, and 14 stand rejected under § 102(e) as anticipated by Corey et al., U.S. Patent No. 6,316,264. To the extent deemed relevant in light of the amended claims, Applicant respectfully traverses this rejection.

Amended claim 1, from which claims 2, 3, 5, and 7 depend, recites "determining if the infrared reflectance of one or more reagents is within an acceptable predetermined range;" and "determining that the test strip is misidentified in the event said infrared reflectance of one or more reagents is outside of the acceptable predetermined range." Amended claim 8, from which claims 9, 10, 12, and 14 depend, recites "determining if said infrared reflectances are within an acceptable predetermined range;" and "determining that said test strip is misidentified in the event said infrared reflectances are outside of the acceptable predetermined range."

Corey et al. do not disclose determining if a strip has been misidentified based on whether infrared reflectances of test / reagent areas are within an acceptable predetermined range. Corey et al. focus on the problem of misalignment of a test strip, rather than determining whether the test strip has been misidentified. Corey et al. state that their "improved test strips

provide a more reliable and accurate constituent assay because the infrared dye ensures that the test strips are properly aligned in an apparatus that detects and measures the test pad response," and that "[t]he present invention is directed to a dry phase test strip that ensures proper alignment of the test strip in a detection apparatus." (Corey et al. col. 1 lines 15-18; col. 3 lines 61-63).

The Office Action cites several passages to support the statement that Corey teaches determining misidentification of a test strip. However, in these passages, Corey instead teaches detecting misalignment, rather than misidentification, of the strip. (See, e.g., Corey et al. col. 3, lines 41-54, describing mispositioning of a test strip). Therefore, Corey et al. do not anticipate the claims.

Hough et al., U.S. Patent No. 6,261,522

Claims 1, 2, 8, 9, 15, 16, 23-25, and 28 stand rejected under § 102(e) as anticipated by Hough et al., U.S. Patent No. 6,261,522. To the extent deemed relevant in light of the amended claims, Applicant respectfully traverses this rejection.

As discussed above, amended claim 1 recites "determining if the infrared reflectance of one or more reagents is within an acceptable predetermined range;" and "determining that the test strip is misidentified in the event said infrared reflectance of one or more reagents is outside of the acceptable predetermined range." Claim 8 similarly recites "determining if said infrared reflectances are within an acceptable predetermined range;" and "determining that said test strip is misidentified in the event said infrared reflectances are outside of the acceptable predetermined range." Amended claim 15 recites "f) determining that said test strip is misidentified in the event said infrared reflectances from said test fields are outside of the predetermined range."

Hough et al. do not disclose determining whether a strip has been misidentified based on whether infrared reflectances of test / reagent fields are within an acceptable predetermined range. Instead, Hough et al. simply determine whether or not any strip is present in a strip reading instrument.

> In one aspect, the invention is directed to an apparatus for automatically detecting the presence of a reagent strip ... and for inspecting the reagent strip after the presence of the reagent strip is detected....

> The invention is also ... provided with a detection system adapted to automatically detect the presence of a reagent strip at a reagent strip receiving area....
>
> In another aspect, the invention ... includes the steps of: (a) automatically detecting the presence of a reagent strip at a reagent strip receiving area....

(Hough et al. col. 1 lines 59-63; col. 2 lines 28-35; 54-67). Moreover, the Hough et al. storage of signals in memory relate to the detection of the presence of a test strip, not to a determinination of whether a test strip has been misidentified. "Each of those illumination signals is [used] ... to determine whether a reagent strip 14 is present in the reagent strip receiving area 12." (Hough et al. col. 6 lines 37-42).

Hough et al. indicate that the purpose of their automatic strip detection is to address the problem of automatic sweeping of an arm of a strip reading instrument.

> In a prior art reagent strip reading instrument marketed by the assignee of this patent under the name "Clinitek 200," ... the blotter arm periodically swept across the area on which reagent strips were placed at a rate of about once every ten seconds, regardless of whether or not a reagent strip was present, and the instrument would generate an audible beep once for every sweep of the blotter arm.

(Hough et al. col. 1 lines 43-52). Accordingly, Applicant respectfully submits that the Hough et al. automatic detection of the mere presence of any strip does not encompass Applicant's claimed determination of strip misidentification.

Since Hough et al. do not disclose determining that a test strip has been misidentified based on whether infrared reflectances of test / reagent areas are within an acceptable predetermined range, Hough et al. do not anticipate the rejected claims.

Rejections under 35 U.S.C. §103(a):

Claims 4, 6, 11, 13, and 18-22

Claims 4, 6, 11, 13, and 18-22 stand rejected under 103(a) as unpatentable over Howard '341. To the extent deemed relevant in light of the amended claims, Applicant respectfully traverses this rejection.

Howard '341 does not teach or suggest every element of the claims. Claims 4 and 6

depend from amended claim 1, which recites "determining if the infrared reflectance of one or more reagents is within an acceptable predetermined range;" and "determining that the test strip is misidentified in the event said infrared reflectance of one or more reagents is outside of the acceptable predetermined range." Claims 11 and 13 depend from amended claim 8, which recites "determining if said infrared reflectances are within an acceptable predetermined range;" and "determining that said test strip is misidentified in the event said infrared reflectances are outside of the acceptable predetermined range." Claims 18-22 depend from amended claim 15, which recites "f) determining that said test strip is misidentified in the event said infrared reflectances from said test fields are outside of the predetermined range."

It is well settled that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP § 2143.03. As discussed above, Howard '341 does not disclose or suggest determining whether a test strip has been misidentified, based on whether the infrared reflectance of reagents are within an acceptable predetermined range. Howard '341 does not disclose determining whether the strip has been misidentified, based on the infrared reflectances of the reagent (test) fields, as claimed. Instead, Howard '341 discloses confirming the identification of the strip based on a coded sequence of marker fields, rather than based on the reagent / test fields. In addition, Howard '341's error reporting step 310 is based solely on reading reflectances of an identification bar code stripe, not on the reflectances of one or more reagents, as claimed.

Therefore, for at least these alternative reasons, Howard '341 does not render Applicant's invention obvious.

CONCLUSION

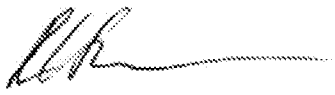
For at least each of the foregoing alternate reasons, Applicant respectfully requests reconsideration and allowance of the pending claims. The dependent claims are believed to be allowable for the same reasons as the independent claims from which they depend, as well as for their own additional limitations. Applicant therefore further submits that all of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered

moot.

This application is now believed to be in condition for allowance, and such action at an early date is respectfully requested. However, if any matters remain unresolved, the Examiner is encouraged to contact the undersigned by telephone.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-0734** referencing Docket No. MSE #2620. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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